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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,397	03/25/2004	Howard R. Levin	JHN-4343-3	5537

23117 7590 04/28/2009  
NIXON & VANDERHYE, PC  
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ARLINGTON, VA 22203

EXAMINER
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DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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04/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/808,397	<b>Applicant(s)</b> LEVIN ET AL.	
	<b>Examiner</b> MATTHEW F. DESANTO	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/12/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5, 8, 11, 13, 15-32, 34-41, and 43-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Aldrich (USPN 6,585,635).

3. Aldrich discloses a method of infusing fluid into the pericardial sac in order to control the heart (Column 2), which constricts the heart because a hydraulic shell is formed around the heart due to the fluid being infused into the pericardial sac (see figure 1, 2 and respective columns).

4. Claims 1-4, 8-11, 13, 15-28, 36-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Snyders (US 6,095,968 A).

5. Snyders discloses a method of infusing fluid into the pericardial sac in order to cause pericardial effusion (Column 1, lines 35-51), wherein the jacket is being interpreted as the catheter, since it is tube like structure with a lumen. The jacket also

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forms a hydraulic shell surrounding the heart in the pericardial sac to reduce dilation of the heart (and entire reference).

6. Column 4, lines 6-30 deals with the pressure transducer and the pressure the jacket is suppose to be maintained between 2-10 mmHg.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5-9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders.

9. Snyders discloses the claimed invention except for the duration of the procedure as well as when to perform the procedure.

10. Therefore at the time of the invention it would have been obvious for one of ordinary skill in the art to modify the teachings of Snyders to include the specific details of the time and length of the procedure. Snyders discloses a method of reducing the ventricular volume of the heart with the specific procedure of infusing fluid into the pericardial sac but fails to recite the specific period of time as well as when to perform the procedure. Therefore it would have been obvious to modify the procedure in Snyder because it only takes routine skill in the medical art and modifications are always made

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when treating a patient, thus the physician must take into account several factors and determine the best type of treatment.

11. Claim 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders.

12. Snyders discloses a gravity fill pump (claim 5), but never recited the height in which the "pump" will be held.

13. At the time of the invention it would have been obvious for one of ordinary skill in the art to modify Snyders because adjusting the height of a gravity pump or hanging reservoir is routinely performed in the medical art and is determined by the medical professional performing the procedure, thus making the modification well known and routine.

14. Claims 29-35, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aldrich (USPN 6,585,635) in view of Igo (USPN 5,900,433).

15. Aldrich discloses the claimed invention except for the catheter that can pierce the pericardial sac.

16. Igo et al. discloses a catheter and a balloon that can pierce the pericardial sac and seal the puncture.

17. At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teaches of Aldrich with the disclosed invention of Aldrich with the teachings of Igo et a. because Igo et al. shows an non-invasive technique to puncture the pericardial sac and reduce the like hood of trauma and complications. The

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technique taught by Igo et al. is a well known technique for infusing drugs or fluid into the pericardial sac and thus would be an obvious modification to the device and teachings of Aldrich.

### ***Response to Arguments***

18. Applicant's arguments with respect to the claims have been considered and are persuasive with regards to Cohen (US 4,991,578 A), and therefore the examiner has withdrawn the rejection of Cohen.

19. With regards to Synders, the examiner disagrees with the interpretation of Synders since the device of Synders is to reduce ventricular output and volume and Synders discloses increasing the pressure in pericardial sac to 2 to 10 mmHg, which is within the same range of pressure being applied to the pericardial sac as the instant application. Therefore the examiner maintains the rejection because the prior art discloses increasing the pressure of the pericardial sac to the same range as the instant invention and thus would create and cause the same effect as the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew F DeSanto/  
Primary Examiner, Art Unit 3763